

**K133972 ASPIRE CRISTALLE**Mar 25, 2014  
89 days to decisionK133972 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k133972/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Dec 26, 2013
Decision date	Mar 25, 2014
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Medical Systems U.S.A, Inc.</b>
Location	Stamford, CT, US
Contact	PETER ALTMAN
510(k) history	39 submissions · 39 cleared · 2005-2018

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